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Through the use of enhanced sensitivity sensors and carefully matched electronics, Active Signal Technologies, under contract with MRMC, devloped and tested a portable Vital Signs Monitor (VSM). The prupose of the VSM is to monitor the condition of casualties at the point of injury and display the two principal vital signs of pulse rate and breathing rate and an additional temperature display that provides an indication of surface temperature. The sensors are contained in a band that is attached to the neck--a site selected in order to avoid the necessity of tearing the casualty's clothing for sensor placement. One sensor rests on the carotid and the other over the larynx. Once in place, the sensor's signals are conditioned and digitized by suitable electronics to count pulse rate, breathing rate, and temperature. The system was tested successfully on patients at the University of Maryland Shock Trauma Center and on pilots at the National Guard Armory at the Aberdeen Proving Grounds. It performed well with an occasional low reading from persons with very faint breathing signals. The next system itneration can include isolating all signals from any ambient noise or motion.

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John McDonald 12-15-98

PI - Signature Date

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1. INTRODUCTION

1.1 Subject

Statistical studies of deaths resulting from injuries received in battle, especially from the Vietnam war, have shown that at least 80% of fatalities occurred within 60 minutes of receiving the injury[1,2]. While many of these service people perished before assistance could reach them, it has been estimated that a significant number (~30%) could have benefited from advanced biomedical intervention in the combat zone[1]. During this critical period immediately after injury, there is a need for continuous and autonomous vital signs monitoring to aid the medic in his diagnosis, provide indications of patient status for early triage, and flag changes in condition which necessitate immediate action. A Vital Signs Monitoring (VSM) device is also the critical element in a system to provide archival data starting at the time of injury, for later review when the combatant arrives at the MASH unit or other echelon of care.

Such a device could be an invaluable aid to the caregiver in the golden hour after injury and help save lives which could otherwise be lost due to inaccurate initial diagnosis, or more critically, through missing life threatening complications such as loss of airway while awaiting evacuation.

Under the present contract, Active Signal Technologies has developed an autonomous, continuous reading vital signs monitor with the capability of measuring heart rate, breathing rate, and temperature. The sensors and signal conditioning support electronics feature an open architecture fully compatible with alarms, future miniaturization, and interface to telemetry systems.

1.2 Purpose

The goal of the research was to design, build and demonstrate a small portable device, that can be used on the battlefield to assess severity of injury and continue updating that assessment while the medic moves onto other patients. The vital signs determined to be most critical in assessing the ABC's (Airway, Breathing, and Circulation) of a trauma victim, given battlefield conditions and a requirement for ultimate simplicity, were pulse, respiration rate and surface temperature. The elements of the system include a monitoring sensor suite, conditioning electronics and the digital processing and display electronics, all housed in a small lightweight package.

The program objectives for each of the sub-elements were:

1. Sensor: The sensors had to be small, unobtrusive, comfortable and readily applied to the neck where an injured soldier would have to undergo minimal disturbance to have them mounted. The sensors had to detect and distinguish between breath and pulse, and sense skin surface temperature.
2. Analog Electronics: The signal conditioning electronics needed had to filter and amplify the pulse and breathing signals for compatability with the digital end of the system. Active Signal had already performed much of this work on the pulse circuit in a parallel, internally funded program, but the breathing circuit required a considerable effort under the contract.
3. Digital Electronics: The a/d boards, microcontrollers and associated components had to process each of the raw analog signals togenerate simple counts in calibrated engineering / medical units.
4. Integrated System: The final system had to be light, portable, independently powered and suitable for testing in the Shock Trauma Center as well as in the field.
5. Interface: The entire electronic architecture had to be kept open enough to remain fully compatible with standard military data transfer and communications requirements.

1.3 Scope of the Research

Active Signal has applied sensor technology from the sonar world to demonstrate a small, automated, non-invasive, vital signs monitor. The scope of the program comprised fabrication and clinical testing of such a system to assess its capability in the combat casualty situation, with the secondary goal of describing the path to its ultimate battlefield miniaturization. Together with this report Active Signal is delivering the sensors and support electronics for the system. An option to complete and deliver a version which would mate to a designated telemetry system was not exercised.

The scope of the research included the following items:

- Build an unobtrusive, neck-mounted sensor suite which could effectively monitor breathing, heart rate and skin surface temperature
- Build the interface electronics, to include the analog and digital components required to acquire, condition, and quantify the physiological data
- Test the device in the University of Maryland Shock Trauma Center (STC) on a minimum of 25 patients
- Discuss implementation of the device in a self contained portable system suitable for combat casualty use

1.4 Background of the Previous Work

The primary driving force behind the present work came from the U.S. Army Rangers approach to Active Signal Technologies personnel with interest in a vital signs monitoring capability to allow the medic to effectively treat numerous casualties, simultaneously while continuously surveying the condition of those not under immediate scrutiny. For instance, the Rangers said a casualty could become destabilized after initial treatment, and in a high noise environment go un-noticed while losing airway and retching. The solution was an ABC monitor light enough for a medic to carry to the battlefield and simple enough to use without interpretive skills. The total system weight would have to be less than 8 oz. and self contained in a pocket size electronics package with unobtrusive, easily applied neck sensors.

We did some initial proof of principle studies with various configurations of low profile bimorph-based physiological sensors and determined that the goal was, in principle, achievable. The results of our investigations were then presented to MRMC in the person of the then Major Steve Bruttig who expressed an interest in the subject. We wrote a white paper and submitted it to MRMC and the effort herein described was begun.

Since that time, we have continued to keep the system and its application visible to medical personnel in the Armed Services through the Special Operations Medical Association (SOMA) Conferences, Advanced Technology Applications for Combat Casualty Care ATACCC Conferences, Army Science Board and Army Medical Department (AMEDD), San Antonio.

2. BODY OF REPORT

2.1 Experimental Methods

The system compromises two major subsystems, the sensor suite / mounting band and the analog / digital support electronics.

2.1.1 Sensor Design

The first step in the development was a review of candidate sensors with potential to detect pulse and breathing. The temperature sensor was preselected as a thermistor based on prior experience.

Table 1 summarizes the evaluation criteria applied and the ratings assigned to each of the sensor types under consideration.

TABLE 1: Evaluation Criteria Used to Downselect Candidate Sensors

Sensor Type	Sensitivity	Noise Rejection	Profile	Maturity of Design	Downselect Rationale
Variable Reluctance	low impedance / good match	poor	acceptable	mature	noise probably too high
Moving Coil	low	not-tested	acceptable	mature	low sensitivity
Geophone	moderate	reasonably good	high	mature	sensitivity/profile a problem
Metglas	low	low	acceptable	immature	sensitivity too low
Bimorph	high	good	good	mature	modified to reduce noise
Fiber Optic					untested
MEMS	low but S/N good	good	good form factor (Amp)	mature	limited bandwidth
Electret Phone	low	good	acceptable	good	low sensitivity
Pretracheal Solid State Sensor	low	good	high	experimental	unsuitable in desired mounting

Several of the more promising candidates were tested, and where the construction of a complete sensor configuration was impractical, key elements of the design were tested independently. Although several sensor types appeared to have desirable attributes when measured against the evaluation criteria, the piezoelectric bimorph ultimately proved to be the most sensitive with reasonable inherent noise rejection, and outstanding flexibility in design. A custom housing was developed for the bimorph element to maximize sensitivity to physiological motion and minimize interference from ambient noise. This sensor is shown in Figure 1 below during the final steps of construction without its housing to illustrate the simplicity of its design.

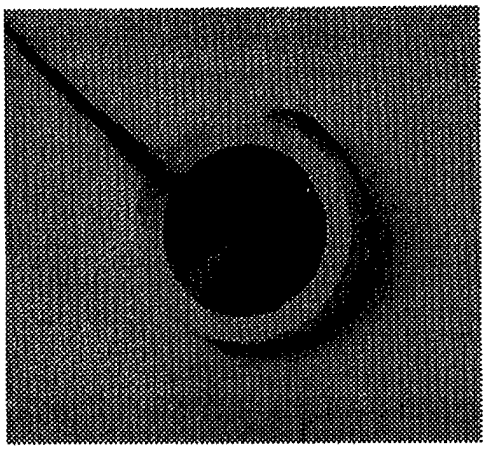

Figure 1. Photograph of the Rear Side of the Bimorph Sensor Showing Mounting and Electroding Scheme

Although the sensing requirements for carotid pulse and tracheal breathing are quite distinct, a bimorph-based design was used for both using different mechanical configurations to adjust the frequency range and absolute sensitivity.

Several elements of the design were addressed in the course of the development:

1. Active Element The piezoelectric bimorph was selected for its sensitivity in the low frequency band. While other piezoelectric sensor configurations, such as accelerometer types that are sometimes used for physiological monitoring, also have good coupling, they do not have this sensitivity at the low end. This is caused principally by an impedance mismatch because the high mechanical impedance accelerometer is measuring activity from a low impedance source of excitation — the physiological disturbance caused by the vital process. The bimorph circumvents this simply by changing the axis of the crystal and depositing it as a thin film on a flexble substrate. The element is then exercised in the bending mode, making it highly sensitive.

2. Housing Several housing options were reviewed and tested extensively through succesive building and ambient noise exposure. Noise rejection was paramount for the breathing sensor because of the very subtle acoustic signal associated with tracheal air movement. Ultimately, a thermoplastic composite casing was found to offer the best natural noise rejection.
3. Sensor to Housing Interface To maximize sensitivity and ruggedness, a custom interface was developed in the housing to mount the active element
4. Weight Since the entire system was ultimately targeted at a weight of less than 8 oz, the sensor mass was kept to approximately 1 oz.
5. Cost While the goal of this project was optimum sensor and electronic performance, ultimate cost was also factored into the material selections and design in view of anticipated high volume production

2.1.2 Electronics Design

The VSM electronics include both analog and digital functionality. Power management considerations in the final device dictated that every attempt be made to minimize the computational burdon on the processor, enabling us to use a simple power efficient microcontroller in place of a more power-hungry, expensive and complex digital signal processing (DSP) chip. Accordingly, most of the signal conditioning functions were assigned to the analog boards wherever feasible. The analog circuits are carefully impedance matched to the electrical load presented by the sensor and thus optimally tuned to receive the physiological signal and reject extraneous noise. In addition, analog components are used to automatically adjust the gain of the input signal to generate usable output even as the physiological signal varies over orders of magnitude in strength. Frequency filtering to select the desired active physiological band is also accomplished on the analog side.

The function of the digital boards is to receive the relatively noise-free and normalized analog signals, sample and digitize them, and then process the output into engineering units for display. For pulse counting, the computational processing includes peak recognition algorithms (typically rising edge and falling edge criteria), peak acceptance criteria (generally, a requirement to drop below a threshold value following the peak), computation of rate, and standard interval selection schemes to ensure reliability in computed averages. For breath recognition and counting, the digital stage operated quite differently. Breaths were recognized by integrating energy content in the 200 - 600 Hz band, establishing a minimum duration and declaring a detected respiration event. As with pulse, breathing rate was determined from breath to breath interval and then averaged over time using interval selection schemes to avoid spurious counts.

A detailed description of the analog and digital circuits used to implement the above functions is provided below, and the overall block diagram of the system is shown in Figure 2.

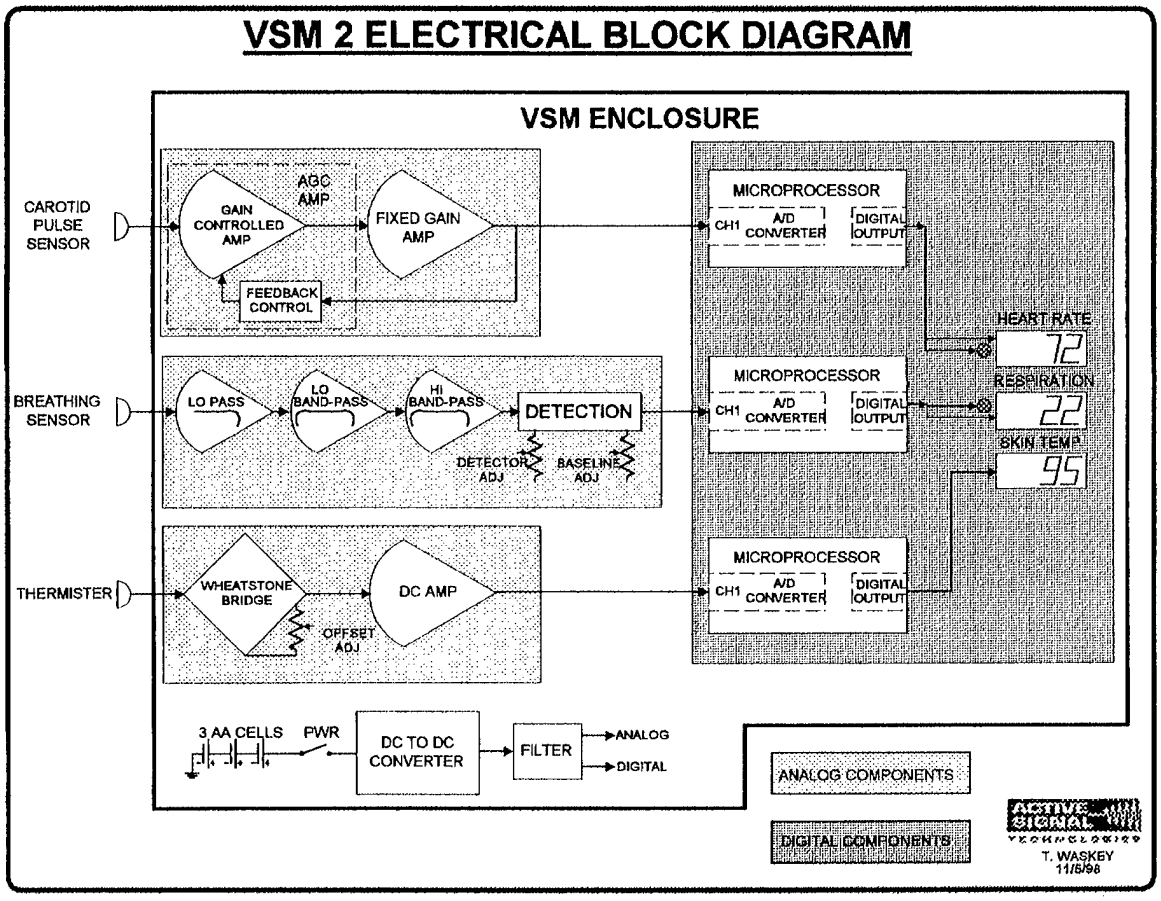

Figure 2. Block Diagram of the Electronics Subsystem

2.1.3 Analog Electronics

The analog board is required to condition the signal from three independent inputs, pulse sensing at the carotid artery, breathing sensing over the larynx, and temperature sensing from a thermistor embedded in the housing of the carotid pulse pick-up.

1) Pulse:

To sense heart rate, the carotid sensor is connected to a two stage amplifier. The first stage is a gain controlled automatic gain control (AGC) amplifier. The AGC compensates for wide differences of pulse amplitude due to person-to-person differences and variations in individual users with position and over time. Its gain can vary from unity, with a strong pulse, to more than 100, with a weak pulse. The input variable used to control the gain of the AGC is the output of the second stage amplifier which feeds back the magnitude of signal that is sensed to the servo on the AGC amplifier. The output of the feedback control produces a control voltage which varies the gain of the first stage. The second stage has a fixed gain of 3.2 and the output is fed to the digital board.

2) Breathing:

For sensing respiration, the breathing sensor is connected to a combination of filters and a peak detector. The first stage is a low pass filter, with a gain of 5, which rolls off the response above 1KHz. This tends to reduce interference from speech. The second and third stages are bandpass filters that are tuned to 400 and 600 Hz respectively; where most of the breathing energy is located. The output of the third stage is fed to a peak detector, which has an adjustable gain (det adj) from 10 to 220. The detector also has offset adjustment (baseline adj), used to reduce any dc offsets from the previous stages. The output of the peak detector is fed to a low pass filter and then to the digital board.

3)Temperature:

For sensing skin temperature, a thermistor is connected to a Wheatstone bridge and then to a dc amplifier. The Wheatstone bridge arrangement allows for a measurement without a precision voltage reference. An adjustment (offset adj) is provided for the calibration of the bridge. The output of the Wheatstone bridge is connected to a differential dc amplifier with a gain of five and the output of the amplifier is fed in turn to the digital board.

2.1.4 Digital Electronics:

The digital board contains the power supply, the three microcontrollers to process each of the sensor signals, three liquid crystal displays (LCD's) and two green light emitting diodes (LED's). The power supply comprises three AA batteries , a power switch, a dc to dc converter, and filters.

The three series connected batteries provide a nominal 4.5 volts input to the dc to dc converter. Over the eight hours of use this voltage will drift down, and the dc to dc converter will boost it to a regulated 5 volts. Output from the converter is filtered and divided into two power feed points: one for the analog board and one for the digital board. The filtering prevents any noise from either the dc to dc converter or the three microprocessors from getting into the analog circuitry.

Each of the signals from the analog board are processed by their own microcontroller dedicated to the one physiological function. The microcontroller chosen is an eight bit microprocessor with analog to digital converter (a/d) and digital output drive. The microprocessor runs at 4MHz, with an instruction rate of one million per second.

The following description applies to all three microcontrollers. Signals from the analog board are fed into the a/d converter portion of each microprocessor. The signal is sampled 200 times a second, over a range of 0 to 5 volts. This signal is converted to an eight bit digital code with a value from 0 to 255. This digital value is then processed by the microprocessor using the appropriate algorithm for each function, and a digital output signal is generated and fed to the LCD. The LCD is updated every three seconds. In the case of the heart rate and respiration functions, a green LED will illuminate each time the sensed signal triggering threshold is exceeded, and turn off once the sensed signal falls below the triggering threshold.

2.1.5 System Integration:

During the development phase, the electronic boards were wired up and interfaced to the sensor system on a large prototyping breadboard. For the final delivery article, the breadboard components were reconfigured into a smaller packaging form factor for user convenience. No micro components or advanced miniaturization techniques were applied. In the ultimate production article, the use of custom printed wiring boards, surface mount components and custom chips will enable another level of product miniaturization.

The fully integrated system is seen in Figure 3, below:

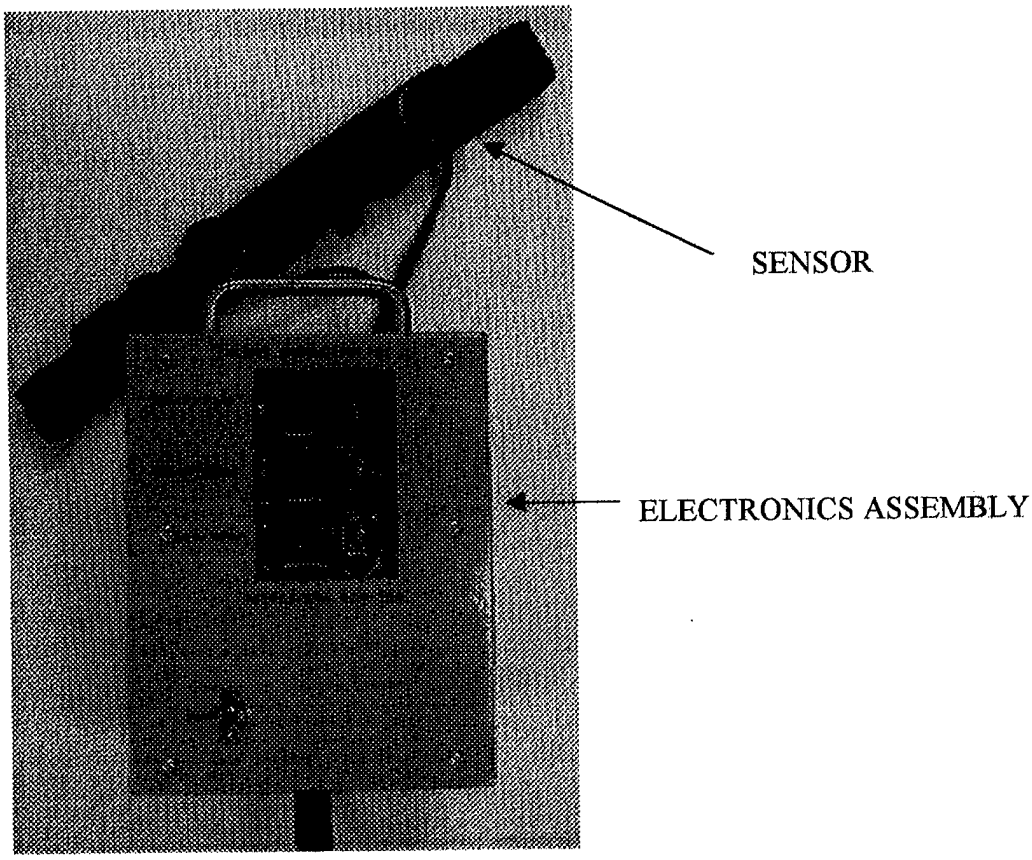

Figure 3. Fully Integrated and Functioning VSM System

2.2 Review of Assumptions

There were a number of important assumptions that served as the underpinning the present project. Without exception, these assumptions were established based on conversations with Army Medical Department personnel from the Medical Research and Materiel Command (MRMC) at Fort Detrick, the Army Rangers, Special Forces and Walter Reed Army Institute of Research (WRAIR).

1. Medical intervention, albeit rudimentary, in the "Golden Hour", or "Brass Ten Minutes" following injury can save the lives of a significant number of battlefield casualties
2. Immediate medical intervention by non-medically-trained soldiers or medics, on the spot, will be more effective when guided by automated continuous electronic monitoring of patient's vital signs
3. In the case of multiple casualties with limited numbers of buddies or care-givers present, automated vital signs monitoring with reliable out-of-limit alarms (red, yellow, green status conditions, as an example) will enable rapid response with life-saving measures and better prioritization of treatment
4. The optimum sensor location for the combat casualty is the neck because this can always be accessed readily except in chemical protective gear where all parts of the body become inaccessible
5. The carrying limitations on the foot soldier demand that the device be extremely small, light and rugged
6. The most important signs to monitor for purposes of rapid intervention with life-saving measures are Airway patency, Breathing (presence or absence of respiration) and Circulation. For expediency in the battlefield environment, it is possible to get adequate information on these conditions by measuring pulse, breathing rate and skin surface temperature
7. Archival data recording of vital signs from the point of injury to the time of admission to a facility with trained medical personnel, will enable more rapid and more effective treatment of trauma victims

2.3 Procedures

Following the sensor and support electronic development described above, the VSM system was tested in a series of different evaluations on both volunteers and hospital inpatients. After each test series, the device was modified to address problems and shortcomings that became apparent during use. After testing in the hospital environment at the University of Maryland Shock Trauma Center, field trials were conducted on volunteers at the Maryland National Guard Armory at Aberdeen Proving Grounds to better gage how the system would perform on the ultimate target population, military personnel. The results of these tests and, where applicable, the interim modifications are reviewed in the following section.

2.4 Results

2.4.1 Test Series No. 1: Subsystem Assessment on Active Signal Technologies' Volunteers

The first, and longest phase of testing involved volunteers from Active Signal Technologies. As the sensors and electronics were progressively developed, breathing, pulse and temperature tests were performed concurrently as a metric of system performance. Below we discuss the development of each subsystem and the measurement methods applied in the assessment.

Temperature:

The skin temperature sensor comprises a standard Thermometrics thermistor designed for physiological monitoring, installed within the side-wall of the pulse sensor. A look-up table was coded into the miniature on-board processor to enable direct Farenheit readout based on measured resistance. While the thermistor settles to its final equilibrium value in about 3 minutes, it rises much more rapidly to a value close to this and tracks slow variations with time quite satisfactorily. Measurements were taken in parallel with a standard commercial Omega 400B-J Digicator and found to compare favorably. In field operation, the skin surface temperature will be valuable in assessing physical condition and health when used in association with core temperature, as measured, for example, with an ingested transmitter pill.

The original tests on skin temperature indicated that the system settled to values on the order of 95 to 97 degrees, values in line with expected skin temperatures, and probably varying more as a function of ambient conditions than sensor dependent differences.

Pulse:

The pulse counter comprises a fairly complex mix of analog and digital processing functions developed for the purpose of accommodating a wide range of input pulse amplitudes and averaging to help discriminate real counts from extraneous noise and motion. The development effort was focused on optimizing coupling mechanisms to improve communication with the carotid artery, strategic filtering of signals, and autogaining to normalize the analog output.

Very thorough testing of the pulse counter was undertaken prior to integration because of the observed individual differences in signal strength and location sensitivity. Therefore the pulse counting system tests were conducted on about 35 people across a spectrum of ages using a wrist mounted sensor for the pickup (the carotid application is less demanding and the sensor uses the same technology). The readings obtained with about 80% of those tested were in agreement with pulse measured by palpation and timing. The remainder were difficult to palpate at the wrist, a problem that is not seen at the neck.

To test the system in a slightly more challenging motion environment, the unit was also tested on two volunteers riding bicycles on a gravel based trail, and gave accurate results with the sensor hand held away from the handlebar.

During early trials on volunteers with the carotid mounting configuration in our own lab, four out of six individuals produced good readings that agreed closely with manual palpating. When the pulse profile of the other two volunteers was examined on an oscilloscope, it was found that the autogain circuit was causing some artificial ripple to be generated in the waveform and detected as separate pulses around systole. This problem was permanently corrected in the analog circuit by slightly damping the speed at which the system responds to change in signal amplitude.

Breathing:

The breathing counter certainly represented the greatest development challenge. Sensor development focused primarily on minimizing its inherent sensitivity to ambient noise, achieved through a combination of very tight analog filtering in the band 200 – 700 Hz, passive noise exclusion, and selective digital sampling. Ultimately, a front-end measurement scheme was implemented for timing the passage of inhale and exhale energy packets in the selected frequency range.

At least 15 different series of tests were conducted on this susystem to optimize the detection of broadband respiration hiss while rejecting competing sources of ambient noise.

2.4.2 Test Series No. 2: Integrated System Assessment on Volunteers at the University of Maryland, National Studies Center for Shock Trauma

After the individual subsystems had been tested, the assembly was taken first to the National Studies Center for Shock Trauma at the University of Maryland Medical System to be tested on Volunteers. The original tests on three volunteers showed sensitivity to low hanging florescent lighting in the hospital and the system was taken back to install a more robust shielding and filtering circuit. Following the system rebuild, it was taken to the recovery room of the Shock Trauma Center where it was tested on 4 individuals as the first in a series of patient tests.

2.4.3 Test Series No. 3: University of Maryland, Shock Trauma Recovery Room and U.S. Army Aberdeen Proving Ground

TABLE 2. VSM Evaluation Test Data

Patient # /Date	Age/Sex	Pulse Actual	Pulse VSM	Breathing Actual	Breathing VSM	Temperature
8/21/'98	33/M*	68-72	68-72	14-16	14-16	96
8/21/'98	40/ F*	68-72	68-72	16-20	16-20	95
8/21/'98	60/M*	78-80	78-80	10-12	10-12	95
8/21/'98	37/M*	74-76	74-76	13-16	13-16	95
10/20/'98	45/M	96-106	94-102	12	15-16	97
10/28/'98	46/M	60	55-61	14	9-11	78**
10/28/'98	67/M	64	61-66	12	18	78
10/28/'98	38/M	59-61	58-64	16-18	11-15	96
10/28/'98	30/M	72	65-74	12	15-20	78
10/28/'98	38/M	68	65-73	16	13-20	78
10/28/'98	39/M	102	97-105	12	15-19	77
10/28/'98	41/F	80	73-84	16-18	12-18	78
10/28/'98	24/F	72	70-83	16-20	18-22	78
11/6/'98	44/M	70	68-75	20	15-19	95
11/6/'98	50/F	70-72	67-74	24	12-20	96
11/6/'98	42/F	88-92	87-94	16	16-18	96
11/6/'98	45/F	72	66-77	14-16	13-21	95
11/6/'98	33/F	76-80	75-84	12-16	16-18	94
11/6/'98	40/F	74-83	80	18-20	17	95
11/10/'98	27/F	64	66-67	28	19-24	95
11/10/'98	49/F	64	62-66	12-12	11-12	96
11/10/'98	42/M	80	74-84	16	18-23	97
11/10/'98	46/M	60	53-62	20	19	94
11/14/'98	51/M	60-64	67	11-12	14-15	95
11/14/'98	34/M	68-72	70-71	19-20	20	96
11/14/'98	32/F	60-68	57-68	14-16	12-16	95
11/14/'98	44/M	76-80	80-83	16-19	16-18	96
11/14/'98	47/F	76	76-77	12	15	95
11/14/'98	34/M	80-82	78-82	12-14	12	94
11/14/'98	35/M	78-80	77-78	12	10-18	96
11/14/'98	46/M	86-88	86-89	12-14	11	95
11/14/'98	36/M	66-72	68-70	12-14	11-13	95
11/14/'98	31/M	76-78	76-81	12-15	16	96
11/14/'98	49/M	64	64-67	20	18	95

*This data was included in the preliminary report submitted to Dr. Frederick Pearce on September 16, 1998

**We found that there was a wire broken during this test series, thus the temperature data from this series showed a large error.

Testing at the Shock Trauma Center was conducted under the IRB approved patient consent criteria. The actual testing was supervised by Dr. William Bernhard and spanned several weeks, beginning on October 2, 1998 and concluding on November 10, 1998. Testing took considerably longer than originally anticipated because many of the Shock Trauma patients had neck braces, precluding the use of a cervically mounted band. Even with these constraints, we were able to test the system on 23 patients at the Shock Trauma Center.

Each patient was fitted with the VSM neck-band, which was adjusted and positioned as necessary to obtain clear triggering on the external LED's, before recording data. Ranges of values on the VSM display for pulse and breathing rates were compared with simultaneous automated invasive data recordings displayed on the hospital patient status monitor. The measurement ranges for VSM and hospital gold standard are shown in the table below. The temperature readings were not correlated with any other measurements since this was surface temperature and most patients under evaluation were not instrumented for continuous temperature monitoring (periodic manual readings of sublingual or aural temperatures were the most common for approximating core temperature).

To round out the device testing on a population more representative of the foot soldiers for whom the device was designed, measurements were taken on Maryland National Guard pilots on November 14, 1998. The results of these tests can be distinguished by date in the table below.

2.5 Discussion

The data shown in Table 2 shows that the pulse counter was generally very reliable and gave values in close agreement either with standard hospital instruments or manual palpation. The sensing technology and electronic counting schemes for this function had been developed under a prior internally funded Active Signal Technologies effort. The method was therefore quite mature and only required adaptation and refinement to the carotid application. In general sensor positioning was very simple and not very sensitive to displacement away from the optimum location, within a radius of about 0.5". Although the pulse counter was designed specifically for an injured soldier lying down fairly motionless, it cannot be assumed that this latter condition will always hold. Accordingly, some measure of motion resistance / motion rejection or cancelation would be desirable.

The breathing counter data from the table is also quite encouraging. Although the match with other independent measures of breathing rate was not always exact, it may, in fact be adequate

for the emergency medical situation. For an injured combatant, it is important to know that respiration is actually taking place. The precise rate is fairly inconsequential. Instead, the ideal system would register "acceptable status" as long as breathing is detected and send out alarms for apnea episodes, inspirational stridor (flagging loss of airway) and other abnormal patterns. Two potential problems have been uncovered that may be responsible for the slight mismatch with the breathing scheme. One is a considerable difference between exhale and inhale acoustic amplitude with some individuals causing a trigger on one but not the other. The other is the type of averaging applied which may lose precision at the very low count rates typical of normal quiet breathing. Nonetheless, these deficiencies can be readily addressed with further development work.

For the target population -- a better conditioned group, more like the National Guard pilots that we tested, the measured vs. actual results were in closer agreement, leading us to believe that the system is well suited for its intended purpose, i.e. the combat casualty.

The current Vital Signs Monitor measures 6" L x 5" W x 4" D and can readily be made smaller. A slightly smaller hand wired unit, could be packaged in a volume of approximately 5" L x 4" W x 2" D, but further reduction would be difficult with through-hole components and internal wiring. For the greatest miniaturization, surface mount technology and printed circuit boards could be used to achieve a size of approximately 3.75" L x 2.5" W x 1.5" D. See figure 4 below.

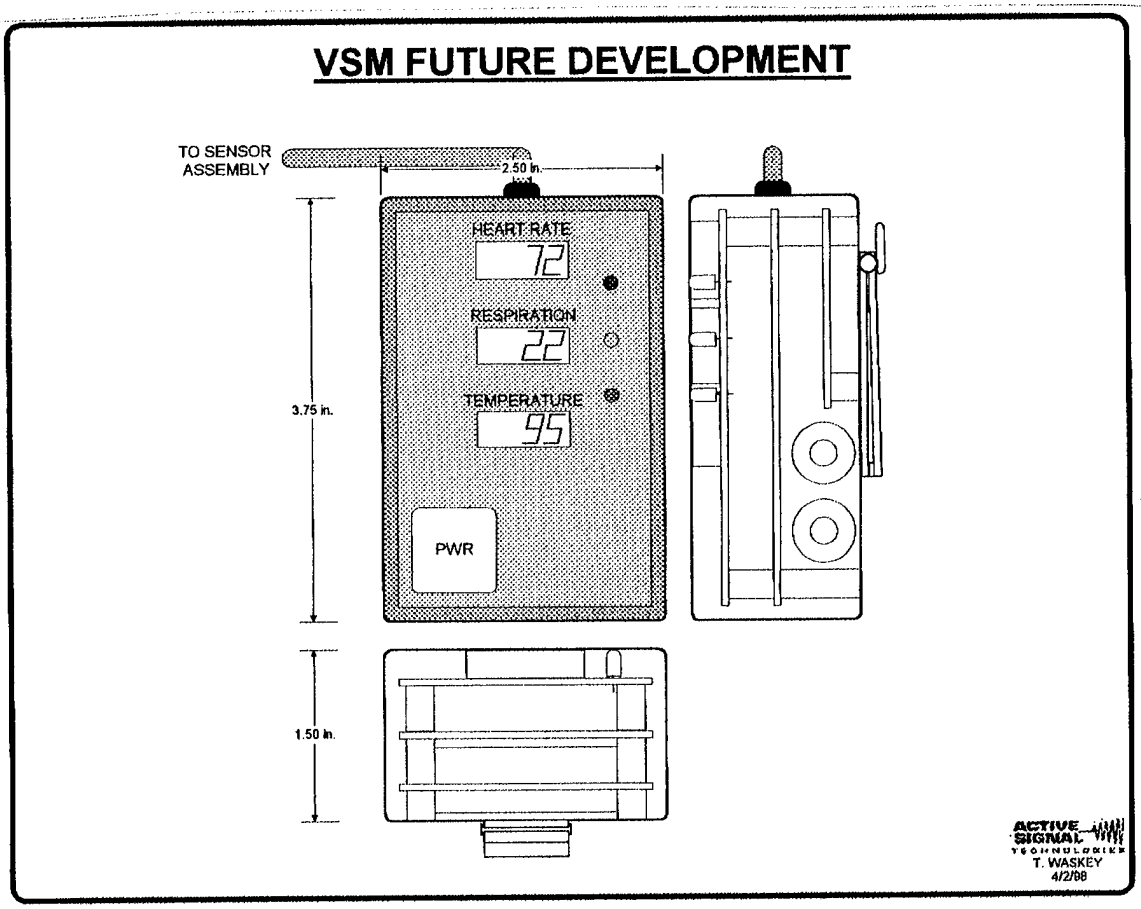

Figure 4. Ultimate Configuration of VSM 'miniaturized' system.

2.6 Problems in Accomplishing the Tasks.

Our greatest challenge in this program was the development of a respiration sensing and counting system. Although the modified bimorph configuration and narrow band frequency capture provided good breath detection over a range of individuals, it proved difficult to set the signal conditioning and counting electronics to capture the very subtle breathing sounds and exclude similar ambient sounds. Ultimately the sensor selected and the electronic settings reflected a compromise that captures most of the population and does especially well on the typical combatant type.

3. CONCLUSIONS

The present program demonstrated feasibility of autonomously measuring injured combatant vital signs using a very small, light and unobtrusive sensor and electronic system. An independently powered, portable prototype with breath-counting, pulse and surface temperature functionality was built, tested on over 25 individuals and delivered. Although well suited for the emergency medical requirement in its present configuration, further development could advantageously produce greater motion immunity in the pulse signal, more accurate respiration rate across a broader population base and further electronic miniaturization.

4. REFERENCES

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5. BIBLIOGRAPHY AND PERSONNEL

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5.2 Personnel Receiving Pay for this Effort

Name	Affiliation	Function
John Sewell	Active Signal Technologies	Principal Investigator
Arthur Cooke	"	Scientist
Keith Bridger	"	Scientist
Ed Passaro	"	Electrical Engineer
Joe Lutian	"	Sensor Developer
Dr. William Bernhard	UMMS	Principal Medical Consultant
Dr. Richard Dutton	"	Associate Medical Consultant